Information for patients participating in the BREATH study

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Dear Sir / Madam,

We kindly ask you to participate in a medical research. You decide whether you want to participate. Before you make the decision, it is important to know more about the research. Read this information letter carefully. Discuss it with partner, friends or family. Do you still have questions after reading the information? Then you can go to the researcher. You will find her contact details on page 3.

What is the purpose of the research?
Various drugs are administered during surgery, including muscle relaxants. These medicines have major effects on the body, including breathing. In this study, which we perform in 30 healthy male test subjects, we investigate the effect of a very low dose of the muscle relaxant rocuronium on breathing. We also look at the effect of reversing muscle relaxation with one of two drugs: neostigmine or sugammadex. Both substances counteract the effect of the muscle relaxant and ensure a return to the normal situation. We measure breathing through a cap on the mouth and nose. During the experiment we regularly stimulate breathing with a small amount of carbon dioxide or with a slight decrease in oxygen concentration. We have extensive experience with these measurements.

The aim of our study is to compare the effect of the two reversing agents (neostigmine and sugammadex) on counteracting the effect of the muscle relaxant on breathing.

How is the research conducted?
1. You get an infusion into a vein of the arm. Via this infusion the muscle relaxant will be administered and also the reversing agents.
2. A band is placed around the upper arm to measure muscle relaxation. This is done through electrical stimulation of the nerve that runs into the upper arm. This is an annoying feeling but this feeling gets used quickly.
3. Patches are stuck to the chest for measuring the heart film and you get a pinch on a finger to measure the oxygen concentration in the blood.
4. We place a cap over nose and mouth. You will receive room air through this cap. We measure your breathing through this cap.
5. Before you are given the muscle relaxant, we will measure your respiratory response for a slight increase in the carbonic acid concentration and a decrease in the oxygen concentration.
6. We then give the muscle relaxant via the drip. The degree of muscle relaxation is low and is comparable with a degree of relaxation that occurs in 40-60% of patients after surgery. The muscle relaxant is administered for 120 minutes and during this administration we repeat the breathing measurements.
7. After 120 minutes we give one of the two reversing agents, neostigmine or sugammadex. The fate will determine which medicine you are given.

8. We repeat the breathing tests again. After the last measurement, the experiment is over. The total experiment takes approximately 200 minutes.
Who is taking part in this study?
Healthy male test subjects can participate in this study.

Side effects
You do not fall asleep during the experiment and you have constant contact with the researchers. It is important to know that you can indicate at any time if you feel uncomfortable and want to stop the experiment. We give it a reversal and you will recover within a few minutes. The experiment is then terminated prematurely and the measurements are discontinued.

You can feel weak in arms and legs. Your head can also feel heavy.

Some subjects experience a slight headache that responds well to acetaminophen.

Sometimes a bruise appears on the site of the drip.

Other side effects that may occur are: dry mouth, salivation, dizziness, blurred or double vision, mild speech impairment (chattering), less deep breathing. Allergic reactions to the medicines we administer are described in the literature. However, this is very rare. We will of course act appropriately and treat the allergic reaction.

If there is reason to do so, we will prematurely relieve muscle relaxation by administering a reversal. This does not end the experiment and our measurements will continue.

compensation
You receive € 250 for a fully completed experiment (1 day). If we or you decide to stop the experiment earlier, you will be paid pro rata (20 euros / hour).

What are the possible pros and cons of participating in this study?
You yourself do not benefit from participating in this study. Possible disadvantages are that you may suffer from side effects during the study. We can treat these side effects well.

Voluntary participation
Your participation in this research is voluntary. If you give permission to this participate in research, you have the freedom to reconsider that decision at any time come. You do not have to give a reason for this.

Insurance
The hospital has taken out an insurance policy that may result in damage can be paid for from the research. If you find that you have suffered damage such as As a result of the research you are participating in (or have participated in), this is best discuss with the researcher.

What happens with your data?

This investigation requires that your medical and personal details are collected and used. Each test subject will receive a code that will appear on the data; your name is omitted. All your data will be treated confidentially If you sign the consent form, you consent to the collection, storage and viewing of your medical and personal data. The researcher will keep your data for 15 years.

Do you want to know anything else?
Would you like independent advice about participating in this study? Then you can contact Dr. E. Sarton (LUMC, department of anesthesiology, tel
071 526 2301). She is not involved in the execution of this study, but she is involved in the state of affairs. It is possible with her the entire procedure calmly
by talking.

Finally
You will receive a copy of the information form and the signed consent form
take it home. If you have any questions regarding this information as a result of this information
research then you can turn to one of us.

Drs. S.J.L. Broens, anaesthesiologist in training
Prof. Dr. Albert Dahan, anaesthesiologist
Department of Anesthesiology, LUMC, P5